MAY 8 2007

K071106

SPECIAL 510(K) SUMMARY

EndoREZ® Dual Cure with Accelerator

This summary of the Special 510(k) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR 807 for EndoREZ Dual Cure with Accelerator.

Applicant's Name and Address

Ultradent Products, Inc.
505 West 10200 South
South Jordan, UT 84095

Contact Person:	Corey Jaseph
Title:	Regulatory Affairs Product Specialist
Telephone:	800-552-5512 x4586, 801-553-4586
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Date Summary Prepared:	April 20, 2007

Name of the Device

Trade Name:	EndoREZ Dual Cure with Accelerator
Common Name:	Resin, Root Canal Filling
Device Classification:	2
Classification Product Code:	KIF

Legally Marketed Predicate Devices to Which Equivalence is Claimed

The predicate device is EndoREZ Dual Cure (K992097 and K042756). This device is manufactured and distributed by Ultradent Products, Inc., 505 West, 10200 South, South Jordan, Utah 84095.

Product Description

A unique biocompatible methacrylate-based root canal sealer/filler, EndoREZ is a two part, mixed, dual cure material with optional EndoREZ Accelerator included. EndoREZ has hydrophilic characteristics providing excellent penetration into dentinal tubules. This allows for improved sealing properties combined with ease of placement and removal. Radiopacity equivalent to gutta percha simplifies radiographic interpretation. EndoREZ does not compromise the function of dentin bonding agents or luting resin polymerization.

Indications for Use

EndoREZ is designed to be used with EndoREZ Points and/or gutta percha for the filling of cleaned and shaped root canals. EndoREZ, in conjunction with a master cone and accessory cones (as needed), provides optimum sealing. Although EndoREZ Points are recommended, EndoREZ may be used with all conventional endodontic obturation techniques.

Table 1: Product Comparison

Property	EndoREZ Dual Cure with Accelerator	Predicate: EndoREZ Dual Cure (K042756)
Intended Use	Root canal sealer/filler	Same
Type of material	UDMA resin	Same
Type of cure	Dual Cure	Same
Characteristics	Hydrophilic and radiopaque	Same
Human factors	Mixed, two-part system in a double syringe	Same
Biocompatibility/Safety	Literature and testing demonstrate product is safe when used as directed	Same

Technological Characteristics

EndoREZ Dual Cure is a methacrylate-based root canal sealer/filler consisting of a two-part, mixed, dual-cure, radiopaque material with hydrophilic characteristics that allow for penetration into dentinal tubules. The formulation of the base and catalyst of the Dual Cure are the substantially the same as in K042756.

An accelerant is being added to the obturation kit and is also available separately that may be used in conjunction with the EndoREZ Dual Cure. The Accelerator will be provided in a unit dose vial (35 µL per vial) for use with EndoREZ Points (or, alternatively, gutta percha). The points (or gutta percha) are dipped into the Accelerator then placed in the root canal. When the Dual Cure comes in contact with the dipped points, the curing reaction is accelerated from 12 – 20 minutes to 4 – 6 minutes.

The Accelerator is comprised of three proprietary elements. Two of the elements are also components of the Dual Cure (a monomer and an inhibitor). The third element is commonly used as an accelerant in polymerization reactions in dental resin fillings and bone cements.

Brief Description of Testing Performed

Each lot of product must pass internal test specifications prior to release. The results of biocompatibility testing demonstrate that the EndoREZ Dual Cure used with the EndoREZ Accelerator is compatible with its intended use as a root canal filler/sealer.

Conclusion and Substantial Equivalence

In conclusion, the EndoREZ Dual Cure used with the EndoREZ Accelerator, to be manufactured and marketed by Ultradent Products, Inc., 505 West 10200 South, South Jordan, UT 84095, is substantially equivalent to the EndoREZ Dual Cure used alone, also manufactured by Ultradent Products, Inc. The two products are composed of nearly the same materials, have the same intended use and technological characteristics, and both are safe and effective when used for the indications described.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 8 2007

Ms. Corey Jaseph
Regulatory Affairs Product Specialist
Ultradent Products, Incorporated
505 West 10200 South
South Jordan, Utah 84095

Re: K071106
Trade/Device Name: EndoREZ Dual Cure with Accelerator
Regulation Number: 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: II
Product Code: KIF
Dated: April 18, 2007
Received: April 23, 2007

Dear Ms. Jaseph:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner

for Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K071106

Device Name: EndoREZ Dual Cure with Accelerator

Indications for Use:

EndoREZ is designed to be used with EndoREZ Points and/or gutta percha for the filling of cleaned and shaped root canals. EndoREZ, in conjunction with a master cone and accessory cones (as needed), provides optimum sealing. Although EndoREZ Points are recommended, EndoREZ may be used with all conventional endodontic obturation techniques.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K071106

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(Posted November 13, 2003)